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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,960	12/22/2000	Michael Strobel	02581-P0350A	8504
7590	05/18/2004			EXAMINER
Wesley W. Whitmyer, Jr. ST. ONGE STEWARD JOHNSTON & REENS LLC 986 Bedford Street Stamford, CT 06905-5619			ODLAND, KATHRYN P	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/745,960	STROBEL ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Kathryn Odland	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 April 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,5,6,8-11 and 14-22 is/are pending in the application.  
 4a) Of the above claim(s) 15-19 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-3, 5, 6, 8-11, 14, and 20-22 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)  
 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.  
 4)  Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5)  Notice of Informal Patent Application (PTO-152)  
 6)  Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment/RCE***

This is a response to the RCE dated April 14, 2004. It is noted that applicant in an After Final Amendment made amendments to the claims. However, the After Final Amendment was not entered. When applicant filed the RCE the amendments made in the After Final Amendment were incorporated and referred to as previously amended, when they are actually currently amended, since the After Final Amendment was not entered.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as depending from a cancelled claim. The art rejection will assume it is depending from claim 1.
3. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9, recites that the bridge is provided in the head portion. However, this does not seem consistent with the figures or the specification. Clarification is required.

***Claim Rejections - 35 USC § 102/103***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 5, 6, 8 and 20-22 are rejected under 35 U.S.C. 102(a and/or e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gresser et al. in US Patent No. 6,241,771.

Regarding claim 1, Gresser et al. disclose a screw (20) for medical purposes having a screw body made of biodegradable material, as recited in column 3, lines 65-67 and column 4. Regarding the phrase, "configured as an interference screw for anchoring a transplant in an opening in a bone." This phrase is considered functional language. Nonetheless, the device of Gresser et al. is an interference screw, since that shown in figures 2A-2C is a screw and the term interference is defined as the act or an instance of hindering, obstructing, or impeding; something that hinders, obstructs, or impedes according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Moreover, the device of Gresser et al. is anchors a transplant in bone. Further, Gresser et al. disclose a device having a head portion having a facial end face, a shaft portion extending from the head portion from an end opposite to the facial end face along an axial direction of the screw body, a threading (such as 21) provided on an outer side of the shaft

portion, as recited in column 4, lines 34-43 and seen in figures 2A-2C; up to five axially extending grooves (26) cut into an outer side of the screw body, as seen in figures 2A and 2C; the up to five grooves extending along the head portion and an entire length of the shaft portion, as seen in figures 2A-2C; at least one recess (23) provided in the facial end face of the head portion; a tool (necessary – as disclosed in column 4, lines 34-42). Thus, it would have a projection corresponding to the recess in the facial end face of the head portion of the screw; the projection can be introduced into the recess for centering the tool on the screw, given the structure. Further, although the drive tool specifics are not explicitly recited, it would be obvious to one with ordinary skill in the art to further have up to five drive elements for inserting into the up to five grooves at least partially for aiding in the insertion of the device.

Regarding claim 2, Gresser et al. disclose that as applied to claim 1, and it is within the scope of the invention and would further be necessary and obvious to one with ordinary skill in the art to assure the depth of the up to at least five axial grooves that are such that the drive element of the driving tool lies within the at least one axially grooves and does not extend beyond an outer periphery of the screw body, for proper insertion given spacial requirements.

Regarding claim 3, Gresser et al. disclose that as applied to claim 1, and it is within the scope of the invention and would further be necessary and obvious

to one with ordinary skill in the art to assure a depth of the at the up to five axially grooves that are such that the drive element of the driving tool is housed within the grooves without extending radially beyond the threading of the shaft portion, for proper insertion given spacial requirements.

Regarding claim 5, Gresser et al. disclose that as applied to claim 1, as well as, a recess (23) that is configured as a channel completely passing through the screw body.

Regarding claim 6, Gresser et al. disclose that as applied to claim 1, as well as, several axially extending grooves (26) that are provided to be distributed uniformly about a circumference of the screw body, as seen in figures 2A-2C.

Regarding claim 8, Gresser et al. disclose that as applied to claim 1, as well as, up to five axially extending grooves that are open axially at the facial end face end of the head portion, as seen in figures 2A-2C.

Regarding claim 20, Gresser et al. disclose a screw (20) having an end face; a shaft extending from the head from an end opposite to the end face along an axial direction perpendicular to the head portion; a threading (such as 21) provided on an outer surface of the shaft; and at least one axially extending groove (26) cut into and extending along an outer side of the head and an entire

length of the shaft, as seen in figures 5 and 6; and a shaft that tapers from the head portion to the end opposite to the end face. Applicant is reminded that the preamble and functional language do not hold patentable weight in apparatus claims. Further, the phrase, "the at least one groove being provided for inserting a drive element of a drive tool therein" is also considered functional language and the grooves Gresser et al. are capable of being used with an insertion tool.

Regarding claim 21, Gresser et al. disclose that as applied to claim 20, as well as at least three grooves, as seen in figures 2A-2C.

Regarding claim 22, Gresser et al. disclose that as applied to claim 21, as well as a head that has at least one recess (23) centered in the end face for receiving a projection on a drive element of the driving tool to center the drive element about the end face.

3. Claims 1-3, 5, 6, 8, 14 and 20-22 are rejected under 35 U.S.C. 102(a and/or e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Simonian et al. in US Patent No. 6,099,530.

Regarding claim 1, Simonian et al. disclose a screw (100) for medical purposes having a screw body made of biodegradable material, as recited in column 3, lines 65-67, column 4, and column 5, lines 35-40. Regarding the phrase, "configured as an interference screw for anchoring a transplant in an

opening in a bone." This phrase is considered functional language.

Nonetheless, the device of Simonian et al. is an interference screw, since that shown in figures 3 is a screw and the term interference is defined as the act or an instance of hindering, obstructing, or impeding; something that hinders, obstructs, or impedes according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Moreover, the device of Simonian et al. is anchors a transplant in bone, as recited in column 3, lines 4-8. Further, Simonian et al. disclose a device having a head portion having a facial end face, a shaft portion extending from the head portion from an end opposite to the facial end face along an axial direction of the screw body, a threading (such as 132/136) provided on an outer side of the shaft portion, as recited in column 4 and seen in figure 3; up to five axially extending grooves (108, 110, 112, 114) cut into an outer side of the screw body, as seen in figure 3; the up to five grooves extending along the head portion and an entire length of the shaft portion, as seen in figure 3; at least one recess (124) provided in the facial end face of the head portion; a tool (necessary – as disclosed in column 4 as not shown). Thus, it would have a projection corresponding to the recess in the facial end face of the head portion of the screw; the projection can be introduced into the recess for centering the tool on the screw, given the structure. Further, although the drive tool specifics are not explicitly recited, it would be obvious to one with ordinary skill in the art to further have up to five

drive elements for inserting into the up to five grooves at least partially for aiding in the insertion of the device.

Regarding claim 2, Simonian et al. disclose that as applied to claim 1, and it is within the scope of the invention and would further be necessary and obvious to one with ordinary skill in the art to assure the depth of the up to at least five axial grooves that are such that the drive element of the driving tool lies within the at least one axially grooves and does not extend beyond an outer periphery of the screw body, for proper insertion given spacial requirements.

Regarding claim 3, Simonian et al. disclose that as applied to claim 1, and it is within the scope of the invention and would further be necessary and obvious to one with ordinary skill in the art to assure a depth of the at the up to five axially grooves that are such that the drive element of the driving tool is housed within the grooves without extending radially beyond the threading of the shaft portion, for proper insertion given spacial requirements.

Regarding claim 5, Simonian et al. disclose that as applied to claim 1, as well as, a recess (124) that is configured as a channel completely passing through the screw body.

Regarding claim 6, Simonian et al. disclose that as applied to claim 1, as well as, several axially extending grooves (108, 110, 112, 114) that are provided to be distributed uniformly about a circumference of the screw body, as seen in figure 3.

Regarding claim 8, Simonian et al. disclose that as applied to claim 1, as well as, up to five axially extending grooves that are open axially at the facial end face end of the head portion, as seen in figure 3.

Regarding claim 14, Simonian et al. disclose that as applied to claim 1, as well as a transplant that is selected from the group of tendon, ligament and combination thereof, as recited in columns 2-3.

Regarding claim 20, Simonian et al. disclose a screw (100) having an end face; a shaft extending from the head from an end opposite to the end face along an axial direction perpendicular to the head portion; a threading (such as 132/136) provided on an outer surface of the shaft; and at least one axially extending groove (108, 110, 112, 114) cut into and extending along an outer side of the head and an entire length of the shaft, as seen in figure 3; and a shaft that tapers from the head portion to the end opposite to the end face. Applicant is reminded that the preamble and functional language do not hold patentable weight in apparatus claims. Further, the phrase, "the at least one groove being

provided for inserting a drive element of a drive tool therein" is also considered functional language and the grooves of Simonian et al. are capable of being used with an insertion tool.

Regarding claim 21, Simonian et al. disclose that as applied to claim 20, as well as at least three grooves, as seen in figure 3.

Regarding claim 22, Simonian et al. disclose that as applied to claim 21, as well as a head that has at least one recess (124) centered in the end face for receiving a projection on a drive element of the driving tool to center the drive element about the end face.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jammet et al. in US Patent No. 5,941,882.

Regarding claim 20, Jammet et al. disclose a screw (120) having an end face; a shaft extending from the head from an end opposite to the end face along an axial direction perpendicular to the head portion; a

threading (116) provided on an outer surface of the shaft; and at least one axially extending groove (118) cut into and extending along an outer side of the head and an entire length of the shaft, as seen in figures 5 and 6.

However, Jammet et al. do not explicitly recite a shaft that tapers from the head portion to the end opposite to the end face. On the other hand, it would be obvious to one with ordinary skill in the art to modify the invention of Jammet et al. to include a taper, for tapering screws are well known in the art, for the purpose of enhanced gripping. Applicant is reminded that the preamble and functional language do not hold patentable weight in apparatus claims. Further, the phrase, "the at least one groove being provided for inserting a drive element of a drive tool therein" is also considered functional language and the grooves of Jammet et al. are capable of being used with an insertion tool.

3. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gresser et al. in US Patent No. 6,241,771 or Simonian et al. in US Patent No. 6,099,530.

Regarding claims 9, 10 and 11, Gresser et al. and/or Simonian et al. disclose that as applied to claim 1 and 8. However, neither Gresser et al. nor Simonian et al. explicitly recite a bridge. However, it would be to one with ordinary skill in the art to provide a bridge for proper alignment.

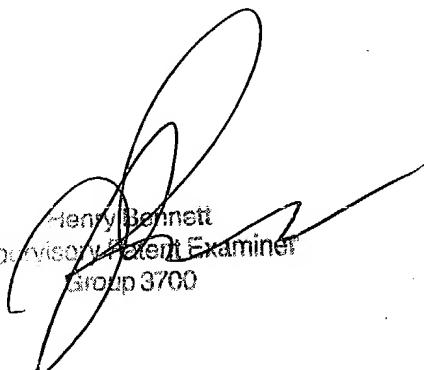
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



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